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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	MARKWELL-040	3546

23869 7590 07/15/2002

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/447,227

Applicant(s)

Shults et al

Examiner

Robert Nasser

Art Unit

3736



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 24, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-24 and 28-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-42 is/are allowed.
- 6) ☒ Claim(s) 21-24 and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12 6) ☐ Other:

Art Unit: 3736

Claims 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 now recites the range exceeding about 30 days to exceeding about 360 days. There is no disclosure of this range and therefore its inclusion in the claim constitutes new matter. Clarification is required.

Claims 32-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 32 recites that the device is "substantially fixated in the foreign body capsule." Applicant's arguments are that the foreign body capsule that form around a smooth device will not substantially fixate the device. The examiner does not follow this reasoning, as the capsule will still hold the device in place. Therefore, the definition of substantially fixated is unclear.

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites the range exceeding about 30 days to exceeding about 360 days. It is unclear exactly what is being claimed, as the range seems redundant. A time period exceeding 360 days necessarily exceeds 30 days. Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3736

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 21-24, 28, 30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Priedel et al. Priedel teaches an implantable glucose in a host where the implantation is for a period of over 360 days (see column 1, lines 19 and 20 in combination with column 1, lines 44 and 45). With respect to claim 32, as applicant noted, a foreign body capsule almost always forms with an implantable device. It seems to the examiner then that the sensor would be in contact therewith.

Claims 21-24, 28, 30, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark. Clark Jr. shows an implantable glucose sensing device capable of continuous glucose sensing for a period of 6 months or more (see column 1, lines 50-55). It is the examiner's position that the foreign body capsule that forms around a device such as Clark Jr. will "substantially fixate" the device, as best as that term can be understood.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3736

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Priedel et al.

It is well known to calibrate an implantable sensor prior to implantation.

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It is well known to calibrate an implantable sensor prior to implantation.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr. in view of Ward et al. Priedel does not use telemetry to transmit the signal out of the body. However, Ward is one of a myriad references that teach that such is a known transmission technique. Hence, it would have been obvious to modify Priedel to use telemetry, as it is merely the substitution of one known equivalent for another.

Claims 33-37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 38-42 are allowable.

Applicant's arguments filed 4/24/2002 have been fully considered but they are not persuasive.

Applicant has asserted that Priedel does not provide an enabling disclosure of a continuous sensing period exceeding 30 days. The examiner disagrees. Column 1, lines 19-20 teaches that medicine calls long term stability sufficient for a 2 year sensing period. Column 1, lines 44 and 45 state that Priedel has the long term stability needed. It follows therefore that Priedel has the stability necessary for a two year sensing period.

Art Unit: 3736

Applicant has further argued that Priedel does not teach continuous glucose monitoring. The examiner disagrees, noting that Priedel senses glucose for the entire period of implantation.

Applicant has also argued that Priedel does not have the size necessary for long-term monitoring. The examiner notes that there is no size restriction in the claims.

In addition, applicant has argued that Priedel would not be operational over a two year period. Such arguments must be presented in the form of evidence. Mere attorney argument is insufficient. See MPEP 716 et seq.

Applicant has also asserted that there is no suggestion in Priedel to calibrate the reference. The examiner agrees, but notes that the suggestion to modify does not need to be explicit in the reference.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

Art Unit: 3736

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is (703) 308-3251. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver, can be reached on (703) 308-2582. The fax phone number for this Group is (703) 308-0758.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [kevin.shaver@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

RLN

July 15, 2002



ROBERT L. NASSER
PRIMARY EXAMINER